

K964544

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**510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
OSTEONICS® SPINAL SYSTEM - VARIABLE OFFSET CONNECTOR ASSEMBLY**

Submission Information**Name and Address of the Sponsor
of the 510(k) Submission:**

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Device Identification**Proprietary Name:**

Osteonics® Spinal System - Variable Offset
Connector Assembly

Common Name:

Spinal Fixation Appliances

Classification Name and Reference:

Spinal Interlaminar Fixation Orthosis
21 CFR 888.3050

Predicate Device Identification

The Osteonics® Spinal System Variable Offset Connector Assembly components are substantially equivalent to other legally marketed spinal system offset components. These predicate components are part of the commercially available spinal systems stated below:

- TSRH™ Spinal System: Sofamor Danek
- ISOLA Spinal System: Acromed

Device Description

The Osteonics® Spinal System Variable Offset Connector Assembly may be used in any application where greater flexibility in bone screw placement is needed. This assembly allows a spinal rod to be joined to a bone screw when variations in the distance between these two components exists. The Variable Offset Connector is provided preassembled with a Ball Ring, which secures into the top of the bone screw. The bone screw is rotated to provide an access to the Variable Offset Connector in conjunction with the longitudinal construct. The Osteonics® Spinal System Clamping Screw is used with the Variable Offset Connector to provide a stable lock on the longitudinal rod.

The connector features a cylindrical arm at one end, a center round hole, and an open-ended split screw hole at the other end. The Ball Ring component is preassembled around the cylindrical arm. The round hole accommodates the spinal rod, and the split screw hole accepts the Clamping Screw, which secures the spinal rod into place.

Intended Use

The subject components of the Osteonics® Spinal System Variable Offset Connector Assembly are single-use devices which are sold non-sterile, and are intended for use only with other components of the commercially available Osteonics® Spinal System. The components of the Osteonics® Spinal System, including the additional components described herein, are available in either ASTM F-138 Stainless Steel (Type 316 LVM) or ASTM F-136 Ti6Al4V ELI Alloy. Stainless steel components are intended for use only with other stainless steel components; Ti6Al4V ELI alloy components are intended for use only with other Ti6Al4V ELI alloy components.

The Osteonics® Spinal System, including the subject additional components, is intended for fixation of the T4-S2 spine. All bone screws are indicated for sacral fixation, or for limited pedicular fixation. When used as a pedicle screw system, the system is intended only for use with autogenous bone graft in order to facilitate fusions of the L5-S1 joint in patients with grade 3 or 4 spondylolisthesis. The screws are not intended for placement in the pedicles above L3, and are intended for removal after development of a solid fusion mass.

Indications

For non-pedicular use:

- Long and short curve scoliosis,
- Vertebral fracture or dislocation,
- Spondylolisthesis,
- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).

For pedicular use:

- When used as a pedicle screw system, the system is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. Pedicle screws are not intended for placement in pedicles above L3.

Statement of Technological Comparison

The components of the Osteonics® Spinal System Variable Offset Connector Assembly share the same materials, intended uses and basic design concepts as that of the predicate devices. Fatigue and static testing demonstrates the mechanical and endurance properties of these components.